

REMARKS

The above claims, as amended, were presented in a response to the Final Office dated December 22, 2003, and accompanied by the requisite extension of time and fee.

Notwithstanding Applicant's explanation in said response that the amended claims presented have either been amended to clarify informalities or are rewritten from former dependent claims, in an Advisory Action the Examiner refused to enter the amendments, opining that these required further search and consideration. Applicant submits that, given the amendments merely correct informalities and rewrite existing claims, such refusal to enter and consider the amendments lacks proper basis. Nonetheless, Applicant has resubmitted its amendments along with an RCE, and reiterates that the amendments add no new matter, and require no further search by the Examiner. A brief discussion of the amendments follows.

Claims 1, 2, and 11-14 have been amended to clarify the steps of Claim 1 so as to conform these claims to the changes in the identifying parenthetical Claim 1 step numbers. No new matter has been added. Entry of this amendment is respectfully requested.

In the Final Office Action dated August 21, 2003, the Examiner indicated that Claims 5 and 6 are allowable provided they are reproduced in independent form. In the above amendments, Applicants have rewritten Claims 5 and 6 as new Claims 16 and 17, respectively. Claim 16 rewrites Claim 5 in independent form incorporating all of the elements and limitations of its base claims. Claim 17 rewrites Claim 6 as dependent upon Claim 16. No new matter has been added, and as these claims were previously considered by the Examiner as allowable, no new search with respect to these claims is required. Consideration and entry of these claims are respectfully requested

Claim 18 rewrites Claim 15 in independent form incorporating all the elements and limitations of Claim 15 and its base claim. No new matter has been added.

With respect to the Examiner's former rejection of this claim as failing to limit the subject matter of its base claim, Applicant's respectfully point out that the recitation of a sequential performance of steps (1) and (2) is a further limitation on the base claim, as unless the steps of a method actually recite an order, the steps are not ordinarily construed to require one. *See Loral Fairchild Corp. v. Sony Corp.*, 181 F.3d 1313, 1322, 50 USPQ2d 1865, 1870 (Fed.Cir.1999). The relevant steps (1) and (2) of claim 1, to which former Claim 15 (now new claim 18) was directed, recite no order or sequence. Applicant submits, therefore, that the limitation presented in Claim 15, (now new claim 18) is a further limitation to the subject matter of Claim 1, and the objection under 37 CFR 1.75(c) is not apt. Reconsideration and withdrawal of this objection is respectfully requested.

Reconsideration and entry of the claims is respectfully solicited.

Rejection Under 35 U.S.C. § 103

The Examiner formerly rejected Claims 1-4, and 7-15 under 35 U.S.C. § 103(a) as being allegedly unpatentable over Bowen et al. (Laboratory Hematology, 1997, hereafter "Bowen") in view of Gopinath et al. (Cytometry, 1997, hereafter "Gopinath"). Applicants continue to respectfully traverse this rejection, and request continued examination so the Examiner may reconsider the rejection based on Applicant's previous arguments and in view of the following additional comments.

Applicants submit that in advancing the rejection the Examiner has not made out a *prima facie* case of obviousness as cited articles fail to account for all claimed elements and exhibit no suggestion or motivation supporting the Examiner's alleged combination. Only speculation and conjecture support the rejection.

In her most recent discussion of the rejection, the Examiner stated that “Bowen et al. differ(s) from the instant invention in failing to teach staining leucocytes after the erythrocytes are removed from the hematological sample.” (Final Action of August 21, 2003, page 5). But the Examiner previously stated in Paper 15, that “Bowen, et al., differs from the instant invention in failing to teach distinguishing eosinophils and neutrophilic cells in the granulocytic cells measured in step (3) [now step (5)] of Claim 1, which were obtained on the basis of scattered light signals and fluorescent intensity of the granulocytic cells.” (Paper 15, Page 5). Curiously, the Examiner’s admission that Bowen fails to teach distinguishing eosinophils and neutrophilic cells in the granulocytic cells measured in step (3) [now step (5)] of Claim 1 was left out of the Examiner’s reiteration of the rejection in the Final Action. Nothing therein indicated the Examiner had reconsidered this point or corrected her position.

Moreover, Applicants pointed out in its prior response that in failing to teach distinguishing eosinophils and neutrophilic cells, Bowen was fatally deficient as a reference (see Applicant’s April 2, 2003 response, page 5), but the Examiner never addressed this argument in the Final Action or in the Advisory Action. The Examiner’s unexplained failure to consider Bowen with respect to each limitation of Applicant’s claim, or to otherwise address this omission in Bowen, appears unwarranted in view of ordinary prosecution practice. Applicants request that their arguments now receive due consideration.

Bowen discloses drawing a gate around a group of granulocytes in a SSC scattergram, which uses anti-CD45 fluorescence, and preparing scattergrams with respect to the granulocytes within the gate which use anti-CD 16 and anti-CD 11b fluorescence. Applicant submits this analysis does not allow for accurate classification and counting of immature granulocytes because of their overlap with eosinophils on the scattergram. As a result, the

method of Bowen seeks left-shifted scattergram immaturity patterns (see page 296, column 2).

Bowen therefore, and at the very least, does not disclose step (5) of Applicants' Claim 1, and, as such, cannot disclose steps (6) or (7), as claimed.

The omission in Bowen, previously admitted by the Examiner, is furthermore not cured by the application of Gopinath. Indeed, the Examiner improperly reads disclosure into Gopinath. The Examiner states that "According to Gopinath, use of lysed whole blood in flow cytometry allows the study of cell surface markers such as CD45, CD16, and CD11b using antibodies to CD45, CD16, and CD11b, respectively, on leucocytic cell populations without using cell purification techniques that may affect expression of these markers." (Final Action, page 5). Gopinath, however, makes no such disclosure, indeed it describes use of anti-CD16 only in its method of distinguishing neutrophils and eosinophils in an SSC scattergram.

However, step (5) of Claim 1, reads: "distinguishing eosinophils and neutrophilic cells in the granulocytic cells obtained in step (4) *on the basis of the intensity of the fluorescence from **the first fluorescence-labeled antibody** and the intensity of the fluorescence from **the second or third fluorescence-labeled antibody**.*" Gopinath lacks this disclosure.

At the very least, neither Bowen nor Gopinath, taken either separately or together, disclose distinguishing neutrophils and eosonophils using two fluorescence based antibodies. Nor do either teach, suggest or motivate this. For this reason alone, these citations do not read on the claimed invention, nor do they render it obvious.

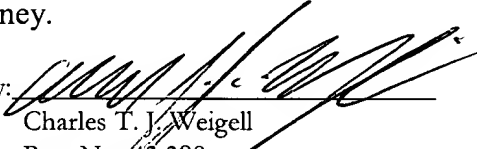
In addition, neither Bowen nor Gopinath disclose classifying *and* counting neutrophilic cells, as recited in the claims. Bowen is concerned with determining maturity scatterplot *patterns*, i.e., a left-shift indication of maturation delay (see Bowen, page 296), compared with specimens from normal marrow. Gopianth is directed to isolation of eosinophils.

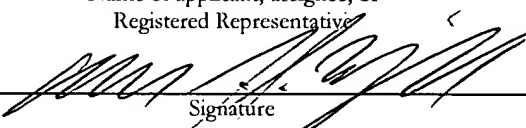
These objectives differ, and as such neither citation is concerned with *classification and counting* of neutrophils by and within maturation groups according to the claims. Even if the citations could be combined to arrive at the claims, i.e., even if they disclosed all claimed elements (which, as demonstrated, they do not), evidence showing motivation to do so is lacking in the citations.

As such, the requirements of a *prima facie* obviousness rejection are clearly unmet here, and the Applicants once again respectfully request the Examiner to reconsider and withdrawn this rejection as to all claims.

CONCLUSION

For the reasons set forth above, entry of the amendments, reconsideration, and allowance of the claims respectfully is requested. If the Examiner has any questions regarding this paper, please contact the undersigned attorney.

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